

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of claims:

1-82. (canceled).

83. (currently amended) A recombinant virus vector that is a lentivirus vector, adenovirus vector, adeno-associated virus vector or replication deficient ~~adeno-virus~~ adenovirus vector comprising two terminal repeat sequences of said virus and a packaging signal of said virus, and a promoter nucleic acid fragment of a mammalian myosin light chain-2 gene comprising nucleotides of approximately residue -19 to approximately residue -800, with respect to the transcription starting point, which corresponds to nucleotide 2406 of SEQ ID NO: 1, of the mammalian myosin light chain-2 gene,

wherein the promoter nucleic acid fragment is operatively linked to the terminal repeat sequences and packaging signal of said virus and is effective for cardiac tissue specific expression of a nucleic acid sequence to be expressed under conditions of somatic gene transfer.

84. (currently amended) ~~The vector of claim 83, wherein the promoter nucleic acid fragment comprises nucleotides of approximately residue 19 to approximately residue 2700, with respect to the transcription starting point, which corresponds to nucleotide 2406 of SEQ ID NO: 1, of the mammalian myosin light chain-2 gene~~A recombinant virus vector that is a lentivirus vector, adenovirus vector, adeno-associated virus vector or replication deficient adenovirus vector comprising two terminal repeat sequences of said virus and a packaging signal of said virus, and a promoter nucleic acid fragment of a mammalian myosin light chain-2 gene comprising a nucleotide sequence corresponding to the nucleotide sequence of nucleotides 158 to 2406 of SEQ ID NO: 1,  
wherein the promoter nucleic acid fragment is operatively linked to the terminal repeat sequences and packaging signal of said virus and is effective for cardiac tissue specific expression of a nucleic acid sequence to be expressed under conditions of somatic gene transfer.

85. (previously presented) A vector comprising the vector pADRSV $\beta$ gal having a DNA fragment comprising nucleotides 1661 to 2405 of SEQ ID NO:1 inserted at the Pvu II restriction enzyme site adjacent to the 3' end of the 1.3 map unit region of the adenovirus type 5 genome.

86. **(previously presented)** The vector according to claim 83, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

87. **(previously presented)** The vector according to claim 84, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

88. **(previously presented)** The vector of any one of claims 83 to 87, further comprising a desired nucleic acid to be expressed that is operatively linked to said promoter.

89. **(currently amended)** The vector according to claim 88, wherein the nucleic acid sequence to be expressed encodes ~~a protein~~ a protein.

90. **(previously presented)** The vector according to claim 89, wherein the protein is selected from a dystrophin, a  $\beta$  adrenergic receptor or a nitric oxide synthetase.

91. **(currently amended)** A recombinant virus vector that is a lentivirus vector, adenovirus vector, adeno-associated virus vector

or replication defective adenovirus vector comprising two terminal repeat sequences and a packaging signal of said virus, and a promoter nucleic acid fragment comprising operatively linked, in the order stated from 5' to 3', the regulatory elements:

HF 1a and 1b consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2340 to 2361 of SEQ ID NO:1;

MLE1 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2229 to 2241 of SEQ ID NO: 1; and

HF 3 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2207 to 2219 of SEQ ID NO: 1; an E box element consisting of nucleotides 2328 to 2333 of SEQ ID NO: 1; and optionally

an HF 2 element consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2271 to 2289 of SEQ ID NO: 1;

wherein the promoter nucleic acid fragment is operatively linked to the two terminal repeat sequences and the packaging signal of said vector and is effective for cardiac tissue specific expression of the nucleic acid sequence to be expressed under conditions of somatic gene transfer.

**92. (previously presented)** The vector of claim 91, further comprising nucleotides of a mammalian myosin light chain - 2 promoter corresponding to the CSS element of nucleotides 682 to

724 of SEQ ID NO: 1 that is operatively linked to the 3' end of the promoter nucleic acid fragment.

93. (currently amended) ~~The vector according to claim 91, A~~  
recombinant replication defective adenovirus vector comprising two  
inverted terminal repeat sequences and a packaging signal of said  
adenovirus, and a promoter nucleic acid fragment comprising  
operatively linked, in the order stated from 5' to 3', the  
regulatory elements:

HF 1a and 1b consisting of nucleotides of a mammalian mlc2  
promoter corresponding to nucleotides 2340 to 2361 of SEQ ID NO:1;

MLE1 consisting of nucleotides of a mammalian mlc2 promoter  
corresponding to nucleotides 2229 to 2241 of SEQ ID NO: 1; and

HF 3 consisting of nucleotides of a mammalian mlc2 promoter  
corresponding to nucleotides 2207 to 2219 of SEQ ID NO: 1; an E box  
element consisting of nucleotides 2328 to 2333 of SEQ ID NO: 1; and  
optionally

an HF 2 element consisting of nucleotides of a mammalian mlc2  
promoter corresponding to nucleotides 2271 to 2289 of SEQ ID NO: 1;

wherein the promoter nucleic acid fragment is operatively  
linked to the two terminal repeat sequences and the packaging signal  
of said vector and is effective for cardiac tissue specific  
expression of the nucleic acid sequence to be expressed under  
conditions of somatic gene transfer~~wherein the virus vector is a~~

~~replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.~~

**94. (currently amended)** ~~The vector according to claim 92,~~ A recombinant replication defective adenovirus vector comprising two inverted terminal repeat sequences and a packaging signal of said adenovirus, and a promoter nucleic acid fragment comprising operatively linked, in the order stated from 5' to 3', the regulatory elements:

HF 1a and 1b consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2340 to 2361 of SEQ ID NO:1;

MLE1 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2229 to 2241 of SEQ ID NO: 1; and

HF 3 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2207 to 2219 of SEQ ID NO: 1; an E box element consisting of nucleotides 2328 to 2333 of SEQ ID NO: 1; and optionally

an HF 2 element consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2271 to 2289 of SEQ ID NO: 1;

and further comprising nucleotides of a mammalian myosin light chain - 2 promoter corresponding to the CSS element of nucleotides 682 to 724 of SEQ ID NO: 1 that is operatively linked to the 3' end of the promoter nucleic acid fragment;

wherein the promoter nucleic acid fragment is operatively

linked to the two terminal repeat sequences and the packaging signal of said vector and is effective for cardiac tissue specific expression of the nucleic acid sequence to be expressed under conditions of somatic gene transfer ~~wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.~~

95. (previously presented) The vector of any one of claims 91 to 94, further comprising a desired nucleic acid to be expressed that is operatively linked to said promoter.

96. (currently amended) The vector according to claim 95, wherein the nucleic acid sequence to be expressed encodes ~~a protein~~ a protein.

97. (previously presented) The recombinant virus vector according to claim 96, wherein the protein is selected from a dystrophin, a  $\beta$  adrenergic receptor or a nitric oxide synthetase.

98. (previously presented) A composition comprising the vector of claim 88, complexed with liposomes.

99. (previously presented) A composition comprising the vector of claim 89, complexed with liposomes.

100. (previously presented) A composition comprising the vector of claim 90, complexed with liposomes.

101. (previously presented) A composition comprising the vector of claim 95, complexed with liposomes.

102. (previously presented) A composition comprising the vector of claim 96, complexed with liposomes.

103. (previously presented) A composition comprising the vector of claim 97, complexed with liposomes.

104. (previously presented) A composition comprising the vector of claim 88 and a pharmaceutically acceptable carrier.

105. (previously presented) A composition comprising the recombinant virus vector of claim 89 and a pharmaceutically acceptable carrier.

106. (previously presented) A composition comprising the recombinant virus vector of claim 90 and a pharmaceutically acceptable carrier.



107. (previously presented) A composition comprising the recombinant virus vector of claim 95 and a pharmaceutically acceptable carrier.

108. (previously presented) A composition comprising the recombinant virus vector of claim 96 and a pharmaceutically acceptable carrier.

109. (previously presented) A composition comprising the recombinant virus vector of claim 97 and a pharmaceutically acceptable carrier.

110. (previously presented) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 88, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

111. (previously presented) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 89, optionally complexed with liposomes, to cardiac tissue, heart blood

vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

**112. (previously presented)** A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 90, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

**113. (previously presented)** A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 95, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

**114. (previously presented)** A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 96, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

115. **(previously presented)** A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 97, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

116. **(previously presented)** The method of claim 110, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

117. **(previously presented)** The method of claim 111, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

118. **(previously presented)** The method of claim 112, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic

cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

**119. (previously presented)** The method of claim 113, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

**120. (previously presented)** The method of claim 114, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

**121. (previously presented)** The vector of claim 83, wherein the promoter nucleic acid fragment comprises nucleotides 1-2405 of SEQ ID NO: 1.

**122. (new)** The vector of claim 83, wherein the promoter nucleic acid fragment comprises nucleotides -19 to -1800, with

respect to the transcription starting point, which corresponds to nucleotide 2406 of SEQ ID NO: 1, of the mammalian myosin light chain-2 gene.

**123. (new)** The vector of claim 83, wherein the promoter nucleic acid fragment comprises nucleotides -19 to -2700, with respect to the transcription starting point, which corresponds to nucleotide 2406 of SEQ ID NO: 1, of the mammalian myosin light chain-2 gene.

**124. (new)** The vector of claim 123, that is a recombinant adenovirus vector, a recombinant adeno-associated virus vector or a recombinant replication deficient adenovirus vector.